IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of: Tobin Island, et al.

Application No.: 10/783,880 Group Art Unit: 3739

Filed: February 19, 2004 Examiner: Henry M. Johnson III

Title: SELF-CONTAINED, EYE SAFE HAIR-REGROWTH INHIBITION APPARATUS AND METHOD

Rule 132 Declaration of Dr. Gary C. Bjorklund

Gary C. Bjorklund declares and states as follows:

1. I am the Consulting Director at the Stanford Photonics Research Center at Stanford University. I am a past president of the Optical Society of America, a past president of the IEEE Lasers and Electro-Optics Society, and I am a Fellow of the Optical Society of America, the Institute of Electrical and Electronics Engineers, and the American Physical Society. I have authored over 100 technical publications, and I am an inventor on over 30 patents. I have served on the National Research Council Committee on Optical Science and Engineering, and I currently serve as the Chair of the Optical Society of America Foundation. I received my undergraduate degree in Physics from M.I.T. in 1968, and I received my Ph.D. in Applied Physics from Stanford University in 1974. My resume is attached hereto as Exhibit A.

2. I have no financial interest in the outcome of this matter, nor do I have any prior relationship with SpectraGenics or any of the inventors of the above-named patent application. I am being compensated for my time at my normal consulting rate.

3. I have made an extensive review of Dr. Michael Slatkine's patent application no. WO 03-049633 (the "'633"). At page 43, lines 13-18, the '633 states the equation for determining eye safety of a laser source, as follows:

> "The AEL for visible and near infrared radiation exiting a diffusing unit for which protective eyeglasses are unnecessary based on an extended diffuser source is defined by ANSI Z 136.1, as 10*k1*k2* (t^1/3) J/cm^2/sr, where t is in seconds and k1=k2=1 for a wavelength of 400-700 nm, k1=1.25 and k2=1 at 750 nm, k1=1.6 and k2=1 at 810 nm, k1=3 and k2=1 at 940 nm and k1=5 and k2=1 at a wavelength of 1060 to 1400 nm. The safety limit set by ISO 15004: 1997 E for pulsed radiation is 14 J/cm^2/sr."

4. I have reviewed ANSI standard Z 136.1. I have also reviewed the standard for laser classifications contained in 21 CFR 1040.10, and I am familiar with its standard for determining whether a laser device is "eye safe" with respect to retinal damage. The '633 is incorrect is attributing the equation set forth in paragraph 4 to ANSI Z 136.1. Instead, this equation is found in 21 CFR 1040.10, which is used the by the CDRH of the FDA to determine whether a laser device is Class I, or "eye safe". Despite the improper attribution of source in the '633, the foregoing equation is stated correctly, and hereinafter, when I use the term "eye safe" I will mean a device whose output satisfies the equation set forth in paragraph 4, above, since this is the standard used by Dr. Slatkine in the '633.

5. The '633 is replete with misunderstandings of optical physics and improperly described designs that are not only not eye safe, but in fact would mislead the reader into building a device which would be extremely dangerous to the eye while believing that it would be eye safe. For the reasons explained below, I have determined that the '633 does not teach even one instance of a device which is eye safe and effective for hair removal under the standard taught by the '633, although it does disclose designs which purport to be eye safe but are not. In fact, a laser which would only damage one eye without the diffuser of the '633 would damage both eyes with the '633's diffuser.

6. One fundamental error in the '633's teachings can be found at page 7, the last sentence of the first full paragraph, where it is stated that:

> "As referred to herein, monochromatic light is defined as being divergent when its exit angle from the distal end of the monochromatic light source, or from the distal end of a diverging unit, when used, is greater than a half angle of 6 degrees, wherein a "half angle" is defined as the half angle measured on a plane perpendicular to the propagation axis of a collimated beam generated by the monochromatic light source. With such a divergent angle, protective eyeglasses having an optical density approximately of only 2 are required for the aesthetc [sic] laser types specified hereinafter, corresponding to a transmittance of 1%. When the divergent half angle is 20 degrees, protective eyeglasses with an optical density of 1 are required, corresponding to a transmittance of 10%. <u>When the divergent half angle is 60 degrees, no protective eyeglasses are required.</u>" [Emphasis added.]

The underlined statement is simply wrong as a matter of optical physics. Lasers, whether laser diodes or other forms of lasers, emit spatially coherent light. Except for very low power lasers, which would not be effective to remove hair, it

is not possible to achieve eye safety merely by increasing the divergence of monochromatic, i.e., laser, light to 60 degrees. Instead, the light (1) must be made spatially incoherent, and (2) must have a sufficiently low fluence. In the context of eye safety, I use the term 'spatially incoherent' to mean that the lens of the eye cannot re-image the light source to a small enough spot on the retina that it will damage the eye. The basic concept is that, as long as the lens of the eye can re-image the light source on the retina as something approaching a point source, the risk of retinal damage exists and the device is not eye safe except at very low fluences.

7. This same fundamental misunderstanding occurs again in the description of Figure 14, found at page 38, where the '633 states:

> "Figure 14 illustrates another preferred embodiment of the invention in which a diffusing unit is not used, but rather a diverging optical element is employed to produce an exit beam having radiance, or alternatively, energy density, depending on the wavelength, below a safe level."

This statement is, again, simply wrong as a matter of physics. Merely using a diverging element, such as a lens, does not render the light source spatially incoherent even if the divergent element results in a half angle of 60°, and does not make it eye safe. If one of ordinary skill in the art were to follow these teachings of the '633, they would believe that they had built an eye-safe device, but in fact that device would be extremely dangerous at fluences sufficient to remove hair. That this error is intentional, and not merely a typographical mistake, is illustrated in Figure 14A, where the divergent element 741 is a simple convex lens. The '633 then states:

> "When divergent beam 742 has a cross sectional dimension at least equal to cross section 752, its radiance is less than an eye safe level."

Again, following this teaching of the '633 would result in a device which is dangerously unsafe to the retina of the eye at any of the fluences used by Dr. Slatkine in his examples that perform hair removal.

8. The device illustrated in Figure 14b of the '633 suffers from a similar misconception, and would not yield an eye safe device at any reasonable fluences. Figure 14b and the associated description, found at page 40, describes an array of reflective lenslets with convex reflectors. The lenslets 992 have a reflective coating 993 on their back side, so that they serve as a divergent reflector. The light reflected through the lenslets 992 strikes a plurality of convex reflectors 995. The rays then exit through transparent plate 994. The intent is to achieve "a safe radiance level" by producing a "divergent half angle of 60

degrees." This, again, evidences a complete misunderstanding of what is required to achieve eye safety under the CFR standard shown in paragraph 4, above. The elements of Figure 14b merely provide divergence. There is no diffusive element at all, and therefore the spatial coherence of the laser source is not destroyed, and the resulting output will not be eye safe. In some respects, the lenslet array of 14b presents even greater risk of eye injury, because each of the lenslets essentially results in a point source that is unsafe, so that, instead of just one unsafe beam, the design of Figure 14b yields an array of unsafe beams. Thus, for example, for a lenslet array of 100 x 100 lenslets placed in front of a laser source of sufficient fluence, the result of Dr. Slatkine's design is 10,000 unsafe beams of light.

9. A related misconception about eye safety is found at page 33 of the '633, where the device of Figure 8b is described as

> "diffuser 784 produces a small diffusing angle of T_2, and refractive/reflective element 785 expands angle T_2 to achieve wide diffusing angle T."

A diffuser with a small diffusing angle is essentially a poor diffuser, and so the teaching of '633 is that a poor diffuser, combined with a refractive/reflective element (i.e., a lens or a mirror) can yield an eye safe device. This is simply not true. The use of the diffuser with a small half angle makes the beam only slightly less coherent and the addition of a lens or mirror only spreads out the beam, it does not make it less coherent. The device of Figure 8b would produce multiple equivalent extended sources, each one of which could be imaged to a small spot on the retina, and would not be eye safe at fluences sufficient to perform a dermatological procedure such as removing hair.

10. The misconception that merely diverging light is the same as diffusing it is repeated at page 49, second paragraph, which states:

> "As can be seen from the above description, a diffusing/diverging unit of the present invention, which is mounted to the exit aperture of a conventional laser unit, induces the exit beam to be divergent/and or scattered at a wide angle. As a result the exit beam is not injurious to the eyes and skin of observers, as well as to objects located in the vicinity of the target."

11. The last paragraph on page 40, which summarizes the teachings of the '633 regarding its eye safe designs, states:

In summation, the present invention incorporates four groups of units which cause a monochromatic light to diverge at a sufficiently wide angle so that the radiance of an exit beam is eye safe:

1) A diverging unit provided with a single diverging optical element;

2) A multi-component diverging unit provided with reflective and refractive optical elements, and without any diffusers;

3) A diffusing unit provided with a single thin diffusively transmitting element; and

4) A multi-component diffusing unit, whereby a wide divergent, diffusing angle is achieved by using a high thermally resistant refractive/reflective optical component, as well as at least one thermally resistant low angle diffuser.

In fact, contrary to the statements made in the '633, there is no disclosure in the '633 that teaches how to make an eye safe device using any of these units, if the fluences are more than a small fraction of those needed to be efficacious for hair removal. Types 1, 2 and 4 are inherently unsafe for the reasons show above. Further, and as discussed in greater detail below, there is no disclosure in the '633 of a single diffusively transmitting element, or type 3, which yields an eye safe unit. In this regard, the '633 teaches nothing about the characteristics of a diffuser, nor does the '633 provide any meaningful guidance to enable one of ordinary skill in the art to build a diffuser to achieve a particular half angle. In my opinion, this lack of teaching is an important omission, because in my opinion one of ordinary skill in the art would not know how build a diffuser with a particular half angle, nor would they know how to deal with less than perfect diffusers, nor the implications of using such imperfect diffusers.

12. At page 43, the '633 asserts that designs taught by the '633 comply with ANSI standard Z136.1 [sic: should be 21 CFR 1040.10] as follows:

> "Staring at the exit of a diffusing unit according to the present invention is equivalent to staring at a reflecting extended diffuser with 100% reflectivity. The AEL for visible and near infrared radiation exiting a diffusing unit for which protective eyeglasses are unnecessary based on an <u>extended diffuser source</u> [sic: extended diffuse source] is defined by ANSI Z 136. 1, as 10*k1*k2* (t**1/3) J/cm^2/sr, where t is in seconds and k1=k2=1 for a wavelength of 400-700 nm, k1=1.25 and k2=1 at 750 nm, k1=1.6 and k2=1 at 810 nm, kl=3 and k2=1 at 940 nm and k1=5 and k2=1 at a wavelength of 1060 to 1400 nm. The safety limit

set by ISO 15004: 1997 E for pulsed radiation is 14 J/cm2/sr." [Emphasis added.]

In fact, the deficiencies pointed out above can be summarized by saying that none of the designs of types 1, 2 and 4 provide an extended diffuse source as required under ANSI standard 136.1 and IEC 60825-1.

13. As noted above, there is no disclosure in the '633 of a single thin diffusely transmitting element, or type 3, above, which yields an eye safe unit. This can be seen by working through the various examples disclosed in the '633 which are described as "eye safe". Some of these can be found in the table set forth at page 45 of the '633. In particular, the '633 teaches that the examples of Table 1 are 'eye safe' if the number in the bottom row exceeds 1. Thus, the examples titled "Non coherent Diode based", and both "Non coherent Nd:YAG based" examples are described as eye safe. However, the table provides values for only an <u>ideal</u> diffuser; see page 44, where it states:

> Table I below presents a comparison in terms of eye safety between the exit beam of monochromatic light after being scattered by a diffusing unit into a solid angle of 3.14 sr, which is equivalent to that attained by an ideal transmitting diffuser, according to the present invention. The

The presentation of numbers for an <u>ideal</u> case is not helpful unless there is also disclosure of how to build an ideal diffuser. Nowhere in the '633 is there any disclosure of how to build an ideal diffuser. In fact, it is well known in the field that commercially available diffusers are typically much less than the ideal. This is true, as well, for the diffusers that the '633 actually discloses; none of the disclosed diffusers is perfect or even close to perfect, and the half angles of the diffusers disclosed by the '633 range between 10 degrees and 40 degrees.

14. Thus, to determine whether the examples given in Table 1 are eye safe, the calculations must be redone for the diffusers that are actually disclosed by the '633. The tables of calculations attached hereto as Attachments I and II show that, for every diffuser actually disclosed by the '633, the resulting device is far from eye safe. In both attachments, the rightmost column shows the ratio of the acceptable emissions limit divided by the calculated emissions limit for the examples in the '633. Thus, for any ratio less than 1, the device is not eye safe. As shown in the tables, none of the examples in the '633 yields a ratio greater than 1. Therefore, none of these examples is eye safe.

15. Because the diffusers in the '633 are imperfect, it is necessary to model their behavior in order to calculate whether the examples given in the '633 will yield an eye safe device. There are two equally valid techniques for modeling the behavior of an imperfect diffuser in combination with a laser source. Thus, for the calculations in Attachment I, the diffuser and light source combination has been modeled as an "Equivalent Extended Source", while in Attachment II the diffuser and light source combination is modeled using a "Subaperture"

technique. While the values in the rightmost column do not agree exactly, the correlation is well within acceptable limits, and both approaches confirm that none of the examples taught in the '633 are eye safe.

16. One of ordinary skill in this art would not typically be able to distinguish the optically correct portions of the '633 teachings from the optically incorrect portions. Instead, one of ordinary skill would likely accept on faith even the incorrect teachings of the '633 application. In my opinion, one of ordinary skill in this art would not know to reject the teachings of the '633 directed to the use of a poor diffuser plus a lens, nor would they understand that the lenslet array yields a dangerous, unsafe device. Further, they would not know to adjust the fluence of the laser source, which is another required modification to the teachings of the '633 in order to yield a device which is eye safe and effective to remove hair. Still further, nothing in the '633 teaches the benefits associated with substantially uniformly illuminating the diffuser, and, again, one of ordinary skill in the art would not know to consider this issue in attempting to build a device which is both eye safe and effective for hair removal. It is not inherent in a light guide that the output has a uniform distribution, and nothing the in '633 teaches how to design such a light guide.

17. As a result, in my opinion the teachings of the '633 are inadequate to teach one of ordinary skill in the art how to build an eye safe device which is effective to remove hair. Stated differently, the teachings of the '633 do not make it obvious to one of ordinary skill in the art how to construct an apparatus that uses a light source to effect hair removal on a human and has an optical diffuser for diffusing the light so that the light emitted from the apparatus is eye safe.

18. I have also reviewed Yaroslavsky Patent Publication 2004-0225339, and particularly Figure 7 and the associated text. The structure shown there does not lead to substantially uniform light distribution, and instead in more used for collimation, similar to the parabolic reflectors used on simple flashlights.

19. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the application or any patent issuing therefrom.

Gary C. Bjorklund

Date: Gary C. Bjorklund 15 May 07

GARY C. BJORKLUND
BIOGRAPHY

Gary C. Bjorklund was born in Passaic, New Jersey in 1946. From 1964-1968, he attended M.I.T., where he majored in Physics, receiving the S.B. degree in June 1968. He started graduate work at Stanford University in the Department of Applied Physics in September 1968 and received the M.S. degree in June 1969. His graduate studies were interrupted by service in the U.S. Army between July 1969 and June 1971. Upon returning to Stanford in June 1971, he joined the research group of Professor S. E. Harris, where he performed thesis research on gas-phase nonlinear optics and vacuum ultraviolet holography, receiving the Ph.D. degree in September 1974.

From October 1974-January 1979, Bjorklund was a member of the Technical Staff at Bell Labs, Holmdel, where he performed research in quantum electronics and nonlinear optics.

In January 1979, he joined the IBM San Jose Research Laboratory (now the IBM Almaden Research Center) as a Research Staff Member and in April 1980 assumed the first of a series of research management positions. During the period from 1980 to 1989, he managed technology development efforts in laser disk optical storage, holographic optical storage, frequency domain optical storage, and materials development efforts in organic materials for laser second harmonic generation. From August 1989 until leaving IBM in July 1994, he was Manager of Organic Optoelectronic Materials and supervised groups pursuing research on polymeric nonlinear optical materials, organic photorefractive materials, and polymeric waveguide electro-optic devices for integrated optics. His personal research interests while at IBM were in applications of photonics for holography, sensitive detection, optical information storage, and optical data communications. As a manager and as an individual contributor, he made major contributions to the development of key intellectual property in the area of applications of photonics for information technology.

In July 1994 he joined the staff of Optivision/Optical Networks in Palo Alto, CA, where he served as Director of Advanced Development, with responsibility for maintaining and establishing new relationships with major government funding agencies in the photonics area; for intellectual property development; and for management oversight of ongoing research in optical switching and networking, guided wave photonics, and photonic interconnects and processors.

In June 1998, he left Optical Networks to found Bjorklund Consulting, Inc. As a consultant, Dr. Bjorklund successfully completed assignments for photonics industry clients such as Anvik, Enablence, SDL, Continuum, Charter Growth Capital, Nanovation Technologies, Norwest Equity Partners, Optical Networks, Gartner Consulting, Focus Ventures, Optikos, Quantum Technology Partners, Symmorphix, Cambridge Research & Instrumentation, Rochester Photonics, and Miramar Venture Partners.

In March 1999, he was elected to the Board of Directors of Nanovation Technologies, Inc., a developer of photonic integrated circuits for telecommunications applications, and appointed Chair of Nanovation's Scientific Advisory Board. From February 2000 to November 2001, he served as Nanovation's Chief Technology Officer, with responsibility for overall technology strategy, for technical outreach, for intellectual property development, and for identifying and evaluating technology partnering opportunities.

Since November 2001, when Nanovation ceased business operations, he has returned to consulting work and is currently engaged with a number of industrial and venture capital clients.

In addition to Nanovation, he has served on the Technical Advisory Boards of several high technology companies: Opthos, Inc., a developer of metro-scale optical networking equipment; Anvik Corp., a manufacturer of large area excimer-laser-based lithography systems; Symmorphix Inc., a developer of amplifying planar waveguide components for optical networks; and Enablence, Inc., a developer of planar waveguide components for fiber to the home/premise applications.

In March 2006, he began on a long term consulting assignment with Stanford University to serve as Consulting Director for the Stanford Photonics Research Center (SPRC). SPRC acts as an interface between the Stanford photonics research community and companies interested in photonics applications. As Consulting Director, he is primarily concerned with SPRC activities in the application areas of solar cells, telecommunications, and information technology.

Dr. Bjorklund is a Fellow of the Optical Society of America, of the Institute of Electrical and Electronics Engineers, and of the American Physical Society. He has authored over 100 technical publications and is an inventor on over 30 patents. In 1998, he was President of the Optical Society of America. He has also served as 1986 President of the IEEE Lasers and Electro-Optics Society, Program Co-Chair of CLEO 1984, General Co-Chair of CLEO 1986, Chair of the 1995 OSA Annual Meeting, and as a member of the OFC Steering Committee. He has been a member of several important advisory committees, including the recent National Research Council Committee on Optical Science and Engineering. He is currently serving as Chair of the OSA Foundation.

FDA CFR Title 21
Analysis of Slatkine
Examples & Table

(Gary C. Bjorklund 23 April 2007)

Equivalent Extended
Source Model

			Calculation of Accessible Emission Limit									Calculation of Actual Exposure				
Example	Diffusing Unit (as described in example)	Assumptions by GCB for FDA Standard Calculations	λ (nm)	t (sec)	θ_D half power angle of diffuser (degrees)	θ_T half power angle of diffusing unit (degrees)	d (mm)	k_1	k_2	AEL_{laser} (J)	$AEL_{extended}$ ($Jcm^{-2}sr^{-1}$)	N (Number of Illuminated Microlens Elements)	q_{av} (Energy Fluence averaged over aperture) (J/cm^2)	Q (Laser energy per pulse) (J)	Ω (Solid angle of emission) (sr)	d_{equiv} (Diameter of equivalent extended source) (mm)
										$AEL=.0007t^{3/4}k_1k_2$	$AEL=10t^{1/3}k_1k_2$			$Q=q_{av}\pi d^2/4$	$\Omega=2\pi(1-\cos\theta_D)$	Example #2 la,IIIa $d_{equiv}=d$ Other Examples $d_{equiv}=dTan\theta_D/Tan60°$
2a	single diffuser (θ = 40 deg)		755	0.0400	40.00	40.00	5.50	1.2500	1.0000	na	4.275	na	25.00	5.940	1.470	5.500
2b	single diffuser (θ = 15 deg)		755	0.0400	15.00	15.00	5.50	1.2500	1.0000	na	4.275	na	25.00	5.940	0.214	5.500
3	diffuser with small scattering angle plus highly divergent lens plus light guide	single diffuser with θ = 15 deg	755	0.0400	15.00	60.00	7.00	1.2500	1.0000	na	4.275	na	25.00	9.621	3.142	1.083
4	array of focusing lenses, an array of lenses with reflective coating on distal side, and a plurality of convex reflectors	no diffuser, array size is 100 x 100	1064	0.1000		60.00	10.00	5.0000	1.0000	0.000622	na	10000	40.00	31.416	na	na
5a(1)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 20 J/cm^2	810	0.0010	40.00	60.00	5.00	1.6000	1.0000	na	1.600	na	20.00	3.927	3.142	2.422
5a(2)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 20 J/cm^2	940	0.0010	40.00	60.00	5.00	3.0000	1.0000	na	3.000	na	20.00	3.927	3.142	2.422
5a(3)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 20 J/cm^2	810	0.2000	40.00	60.00	5.00	1.6000	1.0000	na	9.357	na	20.00	3.927	3.142	2.422
5a(4)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 20 J/cm^2	940	0.2000	40.00	60.00	5.00	3.0000	1.0000	na	17.544	na	20.00	3.927	3.142	2.422
5b(1)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 50 J/cm^2	810	0.0010	40.00	60.00	5.00	1.6000	1.0000	na	1.600	na	50.00	9.817	3.142	2.422
5b(2)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 50 J/cm^2	940	0.0010	40.00	60.00	5.00	3.0000	1.0000	na	3.000	na	50.00	9.817	3.142	2.422
5b(3)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 50 J/cm^2	810	0.2000	40.00	60.00	5.00	1.6000	1.0000	na	9.357	na	50.00	9.817	3.142	2.422
5b(4)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 50 J/cm^2	940	0.2000	40.00	60.00	5.00	3.0000	1.0000	na	17.544	na	50.00	9.817	3.142	2.422
6a	...utilizes an angular beam expander diffuser with a convex reflector, a convex reflector having an inner diameter of 16 mm, a 10 degree glass diffuser, and a light guide...	single diffuser with θ = 10 deg	810	0.3000	10.00	60.00	2.00	1.6000	1.0000	na	10.711	na	30.00	0.942	3.142	0.204
6b	...utilizes an angular beam expander diffuser with a convex reflector, a convex reflector having an inner diameter of 16 mm, a 10 degree glass diffuser, and a light guide...	single diffuser with θ = 10 deg	940	0.3000	10.00	60.00	2.00	3.0000	1.0000	na	20.083	na	30.00	0.942	3.142	0.204
7a	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 40 deg, diverging lens treatment fluence is 10 J/cm^2, pulse duration is 30 msec	694	0.0300	40.00	60.00	10.00	1.0000	1.0000	na	3.107	na	10.00	7.854	3.142	4.845
7b	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 40 deg, diverging lens treatment fluence is 50 J/cm^2, pulse duration is 30 msec	694	0.0300	40.00	60.00	10.00	1.0000	1.0000	na	3.107	na	50.00	39.270	3.142	4.845
7c	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 40 deg, diverging lens treatment fluence is 10 J/cm^2, pulse duration is 0.5 msec	694	0.0005	40.00	60.00	10.00	1.0000	1.0000	na	0.794	na	10.00	7.854	3.142	4.845
7d	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 40 deg, diverging lens treatment fluence is 50 J/cm^2, pulse duration is 0.5 msec	694	0.0005	40.00	60.00	10.00	1.0000	1.0000	na	0.794	na	50.00	39.270	3.142	4.845
7e	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 15 deg, diverging lens treatment fluence is 10 J/cm^2, pulse duration is 30 msec	694	0.0300	15.00	60.00	10.00	1.0000	1.0000	na	3.107	na	10.00	7.854	3.142	1.547
7f	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 15 deg, diverging lens treatment fluence is 50 J/cm^2, pulse duration is 30 msec	694	0.0300	15.00	60.00	10.00	1.0000	1.0000	na	3.107	na	50.00	39.270	3.142	1.547
7g	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 15 deg, diverging lens treatment fluence is 10 J/cm^2, pulse duration is 0.5 msec	694	0.0005	15.00	60.00	10.00	1.0000	1.0000	na	0.794	na	10.00	7.854	3.142	1.547
7h	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 15 deg, diverging lens treatment fluence is 50 J/cm^2, pulse duration is 0.5 msec	694	0.0005	15.00	60.00	10.00	1.0000	1.0000	na	0.794	na	50.00	39.270	3.142	1.547
Table I Column I case a	Non coherent Diode Based	single diffuser with θ = 40 deg	940	0.0500	40.00	40.00	5.00	3.0000	1.0000	na	11.052	na	30.00	5.890	1.470	5.000
Table I Column I case b	Non coherent Diode Based	microlens array, no diffuser, 2500 elements in array	940	0.0500		60.00	5.00	3.0000	1.0000	0.000222	na	2500	30.00	5.890	na	na
Table I Column I case c	Non coherent Diode Based	single diffuser with θ = 15 deg, diverging lens	940	0.0500	15.00	60.00	5.00	3.0000	1.0000	na	11.052	na	30.00	5.890	3.142	0.774
Table I Column III case a	Non coherent Nd:YAG based	single diffuser with θ = 40 deg	1064	0.0600	40.00	40.00	6.00	5.0000	1.0000	na	19.574	na	40.00	11.310	1.470	6.000
Table I Column III case b	Non coherent Nd:YAG based	microlens array, no diffuser, 3600 elements in array	1064	0.0600		60.00	6.00	5.0000	1.0000	0.000424	na	3600	40.00	11.310	na	na
Table I Column III case c	Non coherent Nd:YAG based	single diffuser with θ = 15 deg, diverging lens	1064	0.0600	15.00	60.00	6.00	5.0000	1.0000	na	19.574	na	40.00	11.310	3.142	0.928

			Ratio as Defined by Slatkine (>1 is eye safe)
A_{equiv} (Area of equivalent extended source) (cm^2)	$AR_{adjusted, laser}$ (J)	$AR_{adjusted, extended}$ ($Jcm^{-2}sr^{-1}$)	R (AEL / $AR_{adjusted}$)
$A_{equiv}=\pi d_{equiv}^2/4$	$AR_{adj}=Q/N$	$AR_{adj}=q_{av}/\Omega$	$R = AEL/AR_{adj}$
0.23758	na	17.007	**0.2514**
0.23758	na	116.771	**0.0366**
0.00921	na	332.511	**0.0129**
na	0.003142	na	**0.1981**
0.04608	na	27.125	**0.0590**
0.04608	na	27.125	**0.1106**
0.04608	na	27.125	**0.3449**
0.04608	na	27.125	**0.6468**
0.04608	na	67.813	**0.0236**
0.04608	na	67.813	**0.0442**
0.04608	na	67.813	**0.1380**
0.04608	na	67.813	**0.2587**
0.00033	na	921.415	**0.0116**
0.00033	na	921.415	**0.0218**
0.18433	na	13.563	**0.2291**
0.18433	na	67.813	**0.0458**
0.18433	na	13.563	**0.0585**
0.18433	na	67.813	**0.0117**
0.01880	na	133.005	**0.0234**
0.01880	na	665.023	**0.0047**
0.01880	na	133.005	**0.0060**
0.01880	na	665.023	**0.0012**
0.19635	na	20.408	**0.5415**
na	0.002356	na	**0.0942**
0.00470	na	399.014	**0.0277**
0.28274	na	27.211	**0.7194**
na	0.003142	na	**0.1351**
0.00677	na	532.018	**0.0368**

FDA CFR Title 21
Analysis of Slatkine
Examples & Table

(Gary C. Bjorklund 30 April 2007)

Subaperture Model

Example	Diffusing Unit (as described in example)	Assumptions by GCB for FDA Standard Calculations	λ (nm)	t (sec)	θ_D half power angle of diffuser (degrees)	θ_T half power angle of diffusing unit (degrees)	d (mm)	k_1	k_2	AEL_{laser} (J)	$AEL_{extended}$ ($Jcm^{-2}sr^{-1}$)	N (Number of Illuminated Microlens Elements)	q_{av} (Energy Fluence averaged over aperture) (J/cm^2)	q_{center} (Energy Fluence at central sub-region) (J/cm^2)	Q (Laser energy per pulse) (J)	Ω (Solid angle of emission from sub-region) (sr)
			Calculation of Accessible Emission Limit									Calculation of Actual Exposure				
										$AEL=.0007t^{3/4}k_1k_2$	$AEL=10t^{1/3}k_1k_2$			$q_{center}=1.3863q_{av}$	$Q=q_{av}\pi d^2/4$	$\Omega=2\pi(1-\cos\theta_D)$
2a	single diffuser (θ = 40 deg)		755	0.0400	40.00	40.00	5.50	1.2500	1.0000	na	4.275	na	25.00	34.66	5.940	1.470
2b	single diffuser (θ = 15 deg)		755	0.0400	15.00	15.00	5.50	1.2500	1.0000	na	4.275	na	25.00	34.66	5.940	0.214
3	diffuser with small scattering angle plus highly divergent lens plus light guide	single diffuser with θ = 15 deg	755	0.0400	15.00	60.00	7.00	1.2500	1.0000	na	4.275	na	25.00	34.66	9.621	0.214
4	array of focusing lenses, an array of lenses with reflective coating on distal side, and a plurality of convex reflectors	no diffuser, array size is 100 x 100	1064	0.1000		60.00	10.00	5.0000	1.0000	0.000622	na	10000	40.00	na	31.416	na
5a(1)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 20 J/cm^2	810	0.0010	40.00	60.00	5.00	1.6000	1.0000	na	1.600	na	20.00	27.73	3.927	1.470
5a(2)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 20 J/cm^2	940	0.0010	40.00	60.00	5.00	3.0000	1.0000	na	3.000	na	20.00	27.73	3.927	1.470
5a(3)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 20 J/cm^2	810	0.2000	40.00	60.00	5.00	1.6000	1.0000	na	9.357	na	20.00	27.73	3.927	1.470
5a(4)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 20 J/cm^2	940	0.2000	40.00	60.00	5.00	3.0000	1.0000	na	17.544	na	20.00	27.73	3.927	1.470
5b(1)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 50 J/cm^2	810	0.0010	40.00	60.00	5.00	1.6000	1.0000	na	1.600	na	50.00	69.32	9.817	1.470
5b(2)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 50 J/cm^2	940	0.0010	40.00	60.00	5.00	3.0000	1.0000	na	3.000	na	50.00	69.32	9.817	1.470
5b(3)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 50 J/cm^2	810	0.2000	40.00	60.00	5.00	1.6000	1.0000	na	9.357	na	50.00	69.32	9.817	1.470
5b(4)	...made from fused silica, sapphire, or is a holographic diffuser used in conjunction with a light guide, or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees.	single diffuser with θ = 40 deg, diverging lens, treatment fluence is 50 J/cm^2	940	0.2000	40.00	60.00	5.00	3.0000	1.0000	na	17.544	na	50.00	69.32	9.817	1.470
6a	...utilizes an angular beam expander diffuser with a convex reflector, a convex reflector having an inner diameter of 16 mm, a 10 degree glass diffuser, and a light guide...	single diffuser with θ = 10 deg	810	0.3000	10.00	60.00	2.00	1.6000	1.0000	na	10.711	na	30.00	41.59	0.942	0.095
6b	...utilizes an angular beam expander diffuser with a convex reflector, a convex reflector having an inner diameter of 16 mm, a 10 degree glass diffuser, and a light guide...	single diffuser with θ = 10 deg	940	0.3000	10.00	60.00	2.00	3.0000	1.0000	na	20.083	na	30.00	41.59	0.942	0.095
7a	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 40 deg, diverging lens treatment fluence is 10 J/cm^2, pulse duration is 30 msec	694	0.0300	40.00	60.00	10.00	1.0000	1.0000	na	3.107	na	10.00	13.86	7.854	1.470
7b	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 40 deg, diverging lens treatment fluence is 50 J/cm^2, pulse duration is 30 msec	694	0.0300	40.00	60.00	10.00	1.0000	1.0000	na	3.107	na	50.00	69.32	39.270	1.470
7c	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 40 deg, diverging lens treatment fluence is 10 J/cm^2, pulse duration is 0.5 msec	694	0.0005	40.00	60.00	10.00	1.0000	1.0000	na	0.794	na	10.00	13.86	7.854	1.470
7d	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 40 deg, diverging lens treatment fluence is 50 J/cm^2, pulse duration is 0.5 msec	694	0.0005	40.00	60.00	10.00	1.0000	1.0000	na	0.794	na	50.00	69.32	39.270	1.470
7e	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 15 deg, diverging lens treatment fluence is 10 J/cm^2, pulse duration is 30 msec	694	0.0300	15.00	60.00	10.00	1.0000	1.0000	na	3.107	na	10.00	13.86	7.854	0.214
7f	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 15 deg, diverging lens treatment fluence is 50 J/cm^2, pulse duration is 30 msec	694	0.0300	15.00	60.00	10.00	1.0000	1.0000	na	3.107	na	50.00	69.32	39.270	0.214
7g	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 15 deg, diverging lens treatment fluence is 10 J/cm^2, pulse duration is 0.5 msec	694	0.0005	15.00	60.00	10.00	1.0000	1.0000	na	0.794	na	10.00	13.86	7.854	0.214
7h	A multi-component diffusing or diverging unit may be used.	single diffuser with θ = 15 deg, diverging lens treatment fluence is 50 J/cm^2, pulse duration is 0.5 msec	694	0.0005	15.00	60.00	10.00	1.0000	1.0000	na	0.794	na	50.00	69.32	39.270	0.214
Table I Column I case a	Non coherent Diode Based	single diffuser with θ = 40 deg	940	0.0500	40.00	40.00	5.00	3.0000	1.0000	na	11.052	na	30.00	41.59	5.890	1.470
Table I Column I case b	Non coherent Diode Based	microlens array, no diffuser, 2500 elements in array	940	0.0500		60.00	5.00	3.0000	1.0000	0.000222	na	2500	30.00	na	5.890	na
Table I Column I case c	Non coherent Diode Based	single diffuser with θ = 15 deg, diverging lens	940	0.0500	15.00	60.00	5.00	3.0000	1.0000	na	11.052	na	30.00	41.59	5.890	0.214
Table I Column III case a	Non coherent Nd:YAG based	single diffuser with θ = 40 deg	1064	0.0600	40.00	40.00	6.00	5.0000	1.0000	na	19.574	na	40.00	55.45	11.310	1.470
Table I Column III case b	Non coherent Nd:YAG based	microlens array, no diffuser, 3600 elements in array	1064	0.0600		60.00	6.00	5.0000	1.0000	0.000424	na	3600	40.00	na	11.310	na
Table I Column III case c	Non coherent Nd:YAG based	single diffuser with θ = 15 deg, diverging lens	1064	0.0600	15.00	60.00	6.00	5.0000	1.0000	na	19.574	na	40.00	55.45	11.310	0.214

		Ratio as Defined by Slatkine (>1 is eye safe)
$AR_{adjusted, laser}$ (J)	$AR_{adjusted, extended}$ ($Jcm^{-2}sr^{-1}$)	R ($AEL / AR_{adjusted}$)
$AR_{adj}=Q/N$	$AR_{adj}=q_{center}/\Omega$	$R = AEL/AR_{adj}$
na	23.577	**0.1813**
na	161.880	**0.0264**
na	161.880	**0.0264**
0.003142	na	**0.1981**
na	18.861	**0.0848**
na	18.861	**0.1591**
na	18.861	**0.4961**
na	18.861	**0.9302**
na	47.154	**0.0339**
na	47.154	**0.0636**
na	47.154	**0.1984**
na	47.154	**0.3721**
na	435.689	**0.0246**
na	435.689	**0.0461**
na	9.431	**0.3295**
na	47.154	**0.0659**
na	9.431	**0.0842**
na	47.154	**0.0168**
na	64.752	**0.0480**
na	323.759	**0.0096**
na	64.752	**0.0123**
na	323.759	**0.0025**
na	28.292	**0.3906**
0.002356	na	**0.0942**
na	194.255	**0.0569**
na	37.723	**0.5189**
0.003142	na	**0.1351**
na	259.007	**0.0756**